

REMARKS

Applicant submits that the present amendment is fully responsive to the Office Action dated January 12, 2009 and, thus, the application is in condition for allowance.

By this reply, claims 50, 53, 56, 59, 60, 62 and 65 are amended. Claims 50, 53, 56, 57, 59-62 and 65-67 remain pending. Of the pending claims, claims 50, 53, 59 and 62 are independent. An expedited review and allowance of the application is respectfully requested.

In the outstanding Office Action, the disclosure is objected to for not disclosing the recitation of “the opening in the jaw is partially open” as recited in claims 56, 60 and 65.

Applicant respectfully traverses.

Though not necessarily agreeing with the assertions in the Office Action, and solely to expedite the prosecution of this patent application, Applicant has amended the claims to remove the offending language. The objection should now be withdrawn and the application allowed to issue.

In the outstanding Office Action, claims 56, 60 and 65 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for use of the same offending claim language as recited above. Applicant respectfully traverses.

Though not necessarily agreeing with the assertions in the Office Action, and solely to expedite the prosecution of this patent application, Applicant has amended the claims to remove the offending language. The objection should now be withdrawn and the application allowed to issue.

In the outstanding Office Action, claims 50, 59, 60, 62, 65 and 67 were rejected under 35 U.S.C. § 102(b) as being anticipated by Caspari (U.S. Pat No. 4,923,461). It is asserted that Caspari discloses a device that is substantially the same as the present invention as recited in the

pending claims. Thus, it is concluded that Caspari anticipates the present invention as recited in the present claims. Applicant respectfully traverses.

Using the same reference, claims 61 and 66 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caspari. It is asserted that Caspari discloses all of the features of the recited claims but for an eyelet. It is further concluded that such a feature would have been obvious. Thus, it is concluded that Caspari obviates the present invention as recited in the present claims. Applicant respectfully traverses.

Caspari does not disclose or fairly suggest the present invention as recited in the pending claims because Caspari does not teach a number of features of the present invention as recited in the pending claims. For example, the “opening” in the rigid needle 56 that Caspari uses is in the longitudinal axis of the needle itself, not transversely positioned as recited in the pending claims. See, for example, Caspari, col. 3, lines 50-52 describing a “hollow, tubular needle 56.” Caspari uses this hollow needle to pass suture completely through the hollow needle and out into the tissue (see Caspari, Figures 11-15). In sharp contrast, the present invention uses a transverse opening in the superelastic needle to pass suture through tissue in a perpendicular position as does Caspari. The present invention, as recited in the claims, and that of Caspari use completely different mechanisms of delivering the suture via the needle and to the tissue. Caspari uses the needle to puncture the tissue and then manually push the suture therethrough, and the present invention uses the needle to puncture the tissue and in the process the suture is automatically carried therethrough on the back of the needle (no further manual “forcing” of the suture is required as in Caspari, see col. 5, lines 1-5).

Further, it would not be obvious at all to replace the hollow needle mechanism of Caspari with an “eyelet” because the entire Caspari device is premised exclusively on a hollow needle

mechanism which allows suture to be passed through the hollow tip of the needle. Absolutely no alternatives are provided by Caspari because no alternative non-hollow needle configuration would work. In fact, the hollow needle of Caspari is such a critical feature of its device that it is specifically recited in claims 1-6 and 8-12 (of 12 total claims of the Reexamination Certificate). Caspari would simply fail to operate without a hollow needle.

Furthermore, in Caspari, only the suture and jaws move. The hollow "needle" is firmly attached to the lower jaw and not flexible. The thumb wheel advances the suture through the hollow needle after the needle pierces the tissue. The needle cannot move as it is fixed to the jaw. In fact, the needle does not advance the suture but only provides a channel for some other mechanism (i.e., thumb wheel) to advance the suture. Hence, attaching an eyelet is neither feasible nor obvious with a non-mobile needle. In sharp contrast, the present invention, as provided for in the pending claims, recite multiple elongated structures, one completely slideable within the other, including a slideable needle within the lumen of an outer tubular housing. These recited features in the pending claims are completely absent in Caspari because Caspari's hollow needle is stationary and does not move, let alone slide within the lumen of the Caspari device.

Yet another exemplary distinction between Caspari and the present invention is that during use, the "opening" in the Caspari needle never extends beyond the area between the Caspari device jaws (see Caspari Figures 11-15). In fact, it is impossible for the opening of the needle in Caspari to extend beyond the confines of the Caspari jaws. In sharp contrast, the opening 6 in the puncturing projection is carried completely outside of the area between the jaws 46 and 48 (see Fig. 9A of application). Thus, for at least these reasons, Caspari cannot anticipate

or obviate the present invention as recited in the pending claims because it lacks a number of claimed features of the present invention.

In the outstanding Office Action, claims 53, 56 and 57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caspari in view of Middleman (U.S. Pat. No. 5,820,628). It is asserted that Caspari discloses substantially the same invention as recited in the pending claims but for an elongate member having a first resting configuration, a second stresses configuration and an eyelet. It is further asserted that Middleman does disclose such deficiencies and thus it is concluded that the combination would render the present claims as obvious. Applicant respectfully traverses.

Neither Caspari nor Middleman, nor any other reference of record, alone or in combination, can anticipate or fairly suggest the present invention as recited in the pending claims. Caspari fails as a primary reference because it does not teach the features of the pending claims for at least the reasons stated above. Further, Middleman only shows a flexible needle with no jaw or grasping device whatsoever. All of the Middleman techniques are designed to go around structures rather than pierce through them. In contrast, the Caspari reference discloses pure piercing. Caspari must use a hollow needle and Middleman uses a flexible but solid needle with no opening whatsoever and that must surround its tissue to operate. These are wholly different mechanisms and the substitution of one within the other would simply make the other not work. Thus, the references teach away from each other and cannot be combinable in any way. Neither reference discloses a transversely positioned opening in the piercing needle or projection, as discussed above. Furthermore, the present invention is a single device, and is recited as such, with the features which together produce the desired result. Even if multiple references are used to try to teach every single feature of the presently recited claims, no single

device would be feasible, outside Applicant's own teaching, that would allow all such features to work together in a single device. There is just no motivation or suggestion to completely change how the device in one reference works to combine with the way the device in another reference works. Even if there was such a teaching, *arguendo*, the combination would still not result in the present invention as recited in the pending claims.

A THREE (3) month extension of time is hereby requested to enter this amendment. If any other fees are associated with the entering and consideration of this request for consideration, please charge such fees to our Deposit Account 50-2882.

As all of the outstanding rejections have been traversed and all of the claims are believed to be in condition for allowance, Applicant respectfully requests issuance of a Notice of Allowance. If the undersigned attorney can assist in any matters regarding examination of this application, Examiner is encouraged to call at the number listed below.

Respectfully submitted,

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/Fariborz Moazzam, Reg. No. 53,339/

Fariborz Moazzam

Reg. No. 53,339

Cust. No. 39,013

MOAZZAM & ASSOCIATES, LLC

7601 Lewinsville Road, Suite 304

McLean, VA 22102

(703) 442-9480; (703) 991-5978 (fax)